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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,121	12/23/2004	Marc K. Hellerstein	416272003900(PATENT)	4870
20872	7590	08/08/2006	EXAMINER	
MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482			SHEN, BIN	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/519,121

Applicant(s)

HELLERSTEIN, MARC K.

Examiner

Bin Shen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**DETAILED ACTION**

***Election***

Applicant's election with traverse of Group II, claims 1-6, 10-14, in the reply filed on 6/5/2006 is acknowledged. The traversal is on the ground(s) that the special technical features indicated by the Examiner (disclosed by Scheibner et al.) is not the only common special technical feature. This is not found persuasive because Nanjee et al. (Journal of Lipid Res 2001;42:1586-1593) teach a method for determining the rate of reverse cholesterol transport in humans with isotopically labeled cholesterol via intravenous infusion as claimed in claim 1 (see the following claim rejection-35 USC 102).

The requirement is still deemed proper and is therefore made FINAL.

The IDS received 1/23/2006, 5/11/2005, 4/21/2006, 3/11/2005, the preliminary amendment received 6/10/2005 have been entered.

Claims 7-9 are nonelected, thus they are withdrawn from consideration. Claims 1-6, 10-14 are presented for examination on the merits.

***Specification***

1. The abstract of the disclosure is objected to because the abstract must be a single paragraph. Correction is required. See MPEP § 608.01(b). A new abstract on a separate page is required to replace the current abstract which is the first page of the WO document of the application.

***Claim Rejections - 35 USC § 102***

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 10, 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Nanjee et al. (Journal of Lipid Res 2001;42:1586-1593).

Nanjee et al. teach a method for determining the rate of reverse cholesterol transport in humans with isotopically labeled cholesterol via intravenous infusion (page 1587, left column, 3<sup>rd</sup> full paragraph), obtaining labeled cholesterol from blood (where plasma HDL is obtained) (page 1587, right column, 3<sup>rd</sup> paragraph), measuring and calculating the rate of change of isotopic content (page 1588, left column, 3<sup>rd</sup> paragraph) by liquid scintillation spectrometer (page 1588, left column, end of 2<sup>nd</sup> full paragraph).

Therefore, the cited reference is deemed to anticipate the instant claims above.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the

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art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-6, 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nanjee et al. in view of Hulzebos et al. (Journal of Lipid Res 2001;42:1923-1929).

Nanjee teaches what is above.

Nanjee does not teach the determination of the rate of the second arm of reverse cholesterol transport by administering labeled bile acids to the living system.

Hulzebos et al. teach the measurement of cholic acid kinetics using tetradeuterated cholic acid and its application in rodents and humans. Tetradeuterated cholic acid is administered orally (administered in a different manner than the isotopically labeled cholesterol), (page 1294, right column, 2<sup>nd</sup> full paragraph), plasma is analyzed via mass spectrometry (page 1925, left column, 2<sup>nd</sup> paragraph), and isotope dilution technique (page 1925, left column, 5<sup>th</sup> paragraph) is used to calculate cholic acid kinetics (reflects the changes in cholesterol and bile acid metabolism-see page 1928, right column, 4<sup>th</sup> full paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Nanjee et al. to administer labeled bile acid to the living system as part of the measurement of reverse cholesterol transport because Nanjee teaches that one function of HDL is the transport of cholesterol from peripheral cells to the liver (where it is excreted as bile acid) (second arm of reverse cholesterol transport) (page 1586, left column, 1<sup>st</sup> paragraph of introduction) and Hulzebos teaches a method of labeling bile acid

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to measure cholesterol and bile acid metabolism (see page 1928, right column, 4<sup>th</sup> full paragraph). One would have been motivated to make the modification because Nanjee specifically describe determination of the rate of reverse cholesterol transport using labeled cholesterol and Hulzebos teach a method of determining the kinetics of bile acid to characterize the complete reverse cholesterol transport pathway, and would reasonably have expected success in view of both Nanjee and Hulzebos's teaching.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

#### **Conclusion**

4. No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571)

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272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Terry McKelvey can be reached at (571) 272-0775.

A handwritten signature in black ink, appearing to read 'Michael Meller', followed by a long horizontal line extending to the right.

**MICHAEL MELLER**  
**PRIMARY EXAMINER**

*B Shen*

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